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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/877,935 | 06/08/2001 | Daniel Pinto | 13294-002001 | 1394 |

26191 7590 09/23/2003

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| EXAMINER |
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QIAN, CELINE X

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 09/23/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,935

Applicant(s)

PINTO ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-12 is/are rejected.
- 7) ☒ Claim(s) 2-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-12 are pending in the application.

This Office Action is in response to the Amendment filed on 7/7/03.

Response to Amendment

The rejection of claims 1-12 under 35 U.S.C.101 has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 1-12 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 1, 9-12 under 35 U.S.C.112 1st paragraph (written description) is maintained for reasons set forth of the record mailed on 1/28/03 and further discussed below.

Claims 2-8 are objected to for reasons discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 1, 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the written description requirement is met because the specification has described relationship between promoter function and 9kb

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fragment of the villin gene. Applicants further argue that based on general knowledge of the art, a skilled artisan had the knowledge and tools for isolating promoters at the time the application was filed. Applicants assert that general knowledge about promoter such as TATA and CAAT boxes and promoter deletion assays taught by the specification is sufficient description of the relationship between promoter and its function. Applicants thus conclude that the written description requirement is met.

These arguments have been fully considered but deemed unpersuasive. Claim 1 encompasses a 9kb or smaller fragments 5' of the mouse villin gene that is able to direct tissue specific expression of the mouse villin gene. This genus of nucleotides encompasses 9kb or smaller fragment which may lie inside or outside the 9kb fragment described by the specification (extend from -3.5 to 5.5 kb). The specification fails to describe what specific elements these nucleotides must comprise to confer the promoter activity. General knowledge about promoter such as TATA and CAAT box do not describe a specific tissues expression pattern of the mouse villin gene. Although the specification teaches assays such as promoter deletion experiments wherein a skilled artisan can isolate the fragment having promoter activity, the specification does not teach the structural elements of these nucleotide sequences must share to confer their function of tissue specific expression. A description of an assay that can identify such villin promoter fragments by itself does not demonstrate the possession of these fragments. The invention must be described by its complete structure or other identifying characteristics. The instant specification fails to do that. Similarly, claims 9-12 are rejected for reasons set forth of the record mailed on 1/28/03. Therefore, the written description rejection is maintained.

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Conclusion

Claims 2-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER